

DEC - 8 2000

November 7, 2000
Cool-Tec Bipolar Electrodes

K002841

510(k) Summary

Trade Name: Cool-Tec Bipolar Electrodes

Sponsor: Seedling Enterprises, LLC
150 California Street
Newton, MA 02458
Registration No. not yet assigned

Device Generic Name: Bipolar electrosurgical forcep, grasper

Classification: Class II (878.4400); Electrosurgical and coagulation unit
with accessories
Product Code: GEI

Predicate Devices:

Kirwan Surgical Disposable Bipolar Coagulating Forceps (K900533); Everest Medical Laparoscopic BiCOAG Forceps (K945975); Seedling Cool-tec Monopolar Electrodes (K001723).

Product Description:

The Cool-Tec family of instruments are non-sticking electrosurgical devices that may be used with most commercially available electrosurgical generators. They eliminate sticking of tissue to the electrode by limiting the temperature of the metal electrode tip below the temperature at which tissue sticks to metal. This is done through a heat transfer means that takes the heat generated at the tissue, and transfers it towards the handle for release to the air. These electrosurgical instruments may be used in both minimally invasive and open surgeries to replace currently available bipolar electrosurgical forceps and graspers.

Indications for Use:

Cool-Tec bipolar electrodes are non-sticking, electrosurgical devices intended for grasping and manipulating tissues and providing electrocautery during surgical procedures. They are not for use for contraceptive coagulation of fallopian tube tissue.

Safety and Performance:

Substantial equivalence for these devices was based on similarities in design and performance characteristics as well as performance testing. The materials, performance specifications and essential design characteristics of the Cool-Tec bipolar electrodes are equivalent to those of the predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Cool-Tec bipolar electrodes have been shown to be safe and effective for their intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Seedling Enterprises, LLC.
c/o Ms. Pamela Papineau
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K002841
Trade Name: Cool-Tec Bipolar Electrodes
Regulatory Class: II
Product Code: GEI
Dated: September 7, 2000
Received: September 12, 2000

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

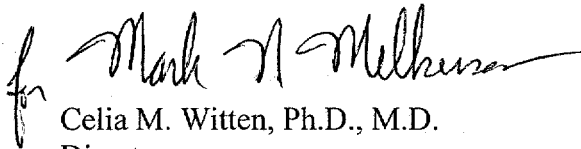
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Pamela Papineau

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Mark N. Melhusen

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K002841

Device Name: Cool-Tec Bipolar Electrodes

Indications for Use:

Cool-Tec non-stick electrodes are biopolar, electrosurgical devices intended for grasping and manipulating tissues and providing electrocautery during surgical procedures.

The proposed devices are not for use for contraceptive coagulation of fallopian tube tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Miller
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K002841

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the -Counter Use ☐

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